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APPLICATION NUMBER: 60/555,979

FILING DATE: March 25, 2004

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

INVENTOR(S)

Given Name (first and middle (if any))	Family Name or Surname	Residence (City and either State or Foreign Country)
ELAN	ZIV MD	RAMAT GAN, ISRAEL

Additional inventors are being named on the _____ separately numbered sheets attached hereto

TITLE OF THE INVENTION (500 characters max)

A SOFT RING FOR PREVENTION OF VAGINAL WALL NECROSIS IN

Direct all correspondence to: CORRESPONDENCE ADDRESS

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ORGAN PROLAPSE

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ENCLOSED APPLICATION PARTS (check all that apply)☒ Specification Number of Pages 8☐ CD(s), Number _____☒ Drawing(s) Number of Sheets 4☐ Other (specify) _____☒ Application Data Sheet. See 37 CFR 1.76**METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT**☒ Applicant claims small entity status. See 37 CFR 1.27.☒ A check or money order is enclosed to cover the filing fees.☐ The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: _____☐ Payment by credit card. Form PTO-2038 is attached.FILING FEE
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\$ 80

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

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(Page 1 of 2)

Respectfully submitted,

Date 21.3.04

SIGNATURE

REGISTRATION NO. _____

TYPED or PRINTED NAME DR ELAN ZIV MD

(if appropriate)

TELEPHONE +972-53-569928

Docket Number: _____

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FEE TRANSMITTAL for FY 2004

Effective 10/01/2003. Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ 80

Complete if Known

Application Number
Filing Date MARCH 12 2004
First Named Inventor Dr Elan Ziv
Examiner Name
Art Unit
Attorney Docket No.

METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☒ Money Order ☐ Other ☐ None

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FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1001 770	2001 385	Utility filing fee	
1002 340	2002 170	Design filing fee	
1003 530	2003 265	Plant filing fee	
1004 770	2004 385	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	80

SUBTOTAL (1) (\$ 80

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
Independent Claims	-20** =	X	
Multiple Dependent	-3** =	X	

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
1202 18	2202 9	Claims in excess of 20
1201 86	2201 43	Independent claims in excess of 3
1203 290	2203 145	Multiple dependent claim, if not paid
1204 86	2204 43	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent

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FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for ex parte reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	
1252 420	2252 210	Extension for reply within second month	
1253 950	2253 475	Extension for reply within third month	
1254 1,480	2254 740	Extension for reply within fourth month	
1255 2,010	2255 1,005	Extension for reply within fifth month	
1401 330	2401 165	Notice of Appeal	
1402 330	2402 165	Filing a brief in support of an appeal	
1403 290	2403 145	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,330	2453 665	Petition to revive - unintentional	
1501 1,330	2501 665	Utility issue fee (or reissue)	
1502 480	2502 240	Design issue fee	
1503 640	2503 320	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	
1807 50	1807 50	Processing fee under 37 CFR 1.17(g)	
1808 180	1808 180	Submission of Information Disclosure Stmt	
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 770	2808 385	Filing a submission after final rejection (37 CFR 1.129(a))	
1810 770	2810 385	For each additional invention to be examined (37 CFR 1.129(b))	
1801 770	2801 385	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	

Other fee (specify)

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SUBTOTAL (3) (\$

SUBMITTED BY

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Date March 14, 2004

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A SOFT RING FOR PREVENTION OF VAGINAL WALL NECROSIS IN TREATMENT OF PELVIC ORGAN PROLAPSE.

The present invention relates generally to the field of treatment of pelvic organ prolapse in female patients. More specifically, the present invention relates to a disposable device for use in the treatment of pelvic organ prolapse in women. The unique invention describes a soft ring covering a vaginal disposable device which is inserted and removed in a no-self-touch technique, by the patient herself, using a disposable applicator.

Inventor: Dr Elan Ziv, MD OBGYN, Urogynecologist

Background of the Invention

General Data

Definition

Pelvic organ prolapse is defined as a condition in which vaginal wall support is lost, and various pelvic organs prolapse into the vagina. This is a very bothering condition, though in most cases it is not a dangerous one. It might appear alone or in combination with urinary stress incontinence.

POP (Pelvic Organ Prolapse) is a very common condition in females, in which various organs, surrounding the vagina, prolapse into it. The reasons for such prolapse are numerous, mainly because the vagina has a very low tensile strength within its walls due to damage to muscles, nerves, fascias etc. There might also be a change within the collagen content, thereby causing a weaker pelvic floor. According to the older definition, prolapse may be divided into five categories, according to the organ that is sagging down (urethra, bladder, uterus, rectum and the pouch of Douglas (small bowl)), and to three grades according to the amount of descent (within the vagina, at the entrance to the vagina, protruding out of the vagina). There might be a combination of various organs prolapse at the same time, with different level of descent. The newer classification (POP-Q) takes into account other factors, such as location of the prolapse and the distance from the entrance of the vagina. There is very little data regarding the prevalence of the problem but it seems to be age related, and older women have much higher tendency towards developing some form of pelvic organ prolapse.

High risk group for Pelvic Organ Prolapse

There are very few statistical & Epidemiological studies regarding the causes for the development of pelvic organ prolapse and high risk groups. The main risk factors are:

- Advanced age
- Pregnancy
- Delivery. During labor, there are many tears, stretchings and hematomas within the muscles, the ligaments and the nerves of the pelvic floor. Instrumental delivery might be a further factor.
- Number of deliveries
- Race. White women tend to have more prolapse than black or oriental women.
- Menopause
- Obesity
- Hard labor.

15 Prevalence

It was found that the prevalence of severe pelvic organ prolapse in women with jobs in labor/factory positions was 11.1%, 6.6% among those working at home, 3.0% in professional/ managerial jobs, 3.3% in service, and 0.8% among technical/sales/clerical workers. Laborers/factory workers had significantly more severe prolapse than the other job categories ($P < .001$). Table 1 summarizes some article on the subject

APPENDIX 1 - Prevalence Rates of POP				
	Samuelsson et al 1999	Bland et al 1999	Progetto Menopausa 2000	Swift 2000
Country	Sweden	U.S.	Italy	U.S.
N	487	241	21,449	497
Age range	20-59	45-55	Around menopause 1	8 - >70
Race				
White	100%	89%	100%	47%
Black		9%		52%
Parcus	54%	Unspecified	85.6%	93%
Hysterectomy	4%	28%	None	28%
Staging technique	Above, to, beyond hymen	ICS	Uterus only Baden 0, 1, 2, 3	ICS
Stage				
0	71.2%	73%	94.5%	6.4%
1	28.8%	23%	3.6%	43.3%
2	2%	4%	1.9%	47.7%
3	0	0		2.6%
4	0	0		0
Source of subjects	76% of every 3 year screen participants	Responded to ad for soybean supplement study	268 first-level menopause clinics in Italy.	Routine gynecologic examination

TABLE 1

"A soft ring for prevention of vaginal wall necrosis in treatment of pelvic organ prolapse"
Dr Elan Ziv, MD OBGYN, Urogynecologist

Page 2 of 8

Anatomy and pathophysiology

Understanding the female genital anatomy is extremely important in order to understand the basis of this invention.

FIG. 1A is an anatomical frontal cut section of the vagina

5 FIG. 1B is a front view of vagina creating the shape of the letter H.

FIG. 1C is a side view of the vaginal diameters.

FIG. 2 is a side view of the female pelvis.

10 The vagina is a hollow organ with multiple shapes and diameters at different depths. The sidewalls (FIG.1A) have thin longitudinal and circular muscles (8), externally wrapped by the pelvic fascia (10), which tends to become weakened, stretched and attenuated over the years and allow for sagging and prolapse of different pelvic organs into and through the vagina. Internally the vagina is covered with the mucosa (6).

15 Although potentially being a tube, the vaginal cavity is almost always obliterated with the anterior wall (12) and the heavy bladder on it collapse and fall into the vaginal lumen. The posterior wall is pushed anteriorly by the bowel (14), thereby creating the shape of the letter H (FIG.1B). Vaginal diameters, either lateral or antero-posterior (FIG.1C, FIG.2) are never the same along vaginal axis. Lateral diameter is usually shorter closer to the entrance (18) gradually becoming longer internally (16). The same
20 applies for the antero-posterior diameter, while diameter close to the entrance (44) is usually shorter than the one behind the perineal body (48). The vagina may therefore be looked at as a funneled shape organ.

25 There are certain defined organs in direct contact with the vagina or within short proximity. The bladder (36) is a hollow, sack like organ, in which the urine is accumulated prior to it's expulsion outside the body through the urethra (42). The bladder is located behind the pubic bone (38) and rests on the middle third of the vagina. The urethra is a short muscular pipe, 25-35 mms in length, in direct contact with the bladder at the bladder neck (40) resting on the lower third of the anterior vaginal wall, in direct contact with the pubic bone. The uterus (30) is a pear shaped organ that
30 has a lower part, the cervix (32) which protrudes into the dome of the vagina. The body of uterus is an abdominal organ, which, in most cases bands forward on the bladder. The cervix, while protruding into the vagina creates 4 fornices – 2 laterals which are of the same dimensions, one smaller anterior (34), and one posterior (22), which is actually

5 behind the cervix. The posterior fornix has direct contact with the pouch of Douglas (20) which is the deepest part of the abdominal cavity, on top of the vagina. The posterior surface of the vagina is in contact with the rectum (24), until the area where a thick muscular body, the perineal body (26) which is part of the pelvic floor and the sphincter of the anus (28).

10 Prolapse of adjacent organs into the vagina is quite common, in variable degrees. The reasons for such a prolapse are mainly damage to the endopelvic fascia which surrounds the organs and keeps them in the right position, pelvic floor muscular damage, and neural damage. Prolapse of the urethra, named urethrocel, is one of the several possibilities for pelvic organ prolapse around the vagina. The most frequent prolapse is of the bladder, named cystocele, as a result of its weight. Prolapse of posterior fornix, with bowl inside is called enterocele, and prolapse of the posterior vaginal wall with the rectum in it is termed rectocele. When the ligaments that hold the uterus in place
15 weaken, a uterine descent occurs. In cases where the uterus has been removed, and the vagina is dome shaped, a vault prolapse may occur.

Current treatment

At present – there are 2 ways of dealing with Pelvic Organ Prolapses:

- 20 1. Surgical – vaginal or abdominal
2. Use of vaginal devices (pessaries) that are inserted into the vagina and mechanically reduce the prolapse by pushing the wall aside and upwards.

Efforts to avoid surgical procedures have resulted in the development of a number of non-surgical vaginal devices, inserted into the vagina by the surgeon or the patient.

25 Vaginal devices are well known for their tremendous diversity in shapes and sizes. These devices are meant to prevent prolapse of the vaginal walls, with different location of pressure application.

Some of these devices tend to block all flow of urine from the bladder. Therefore, when a patient needs to urinate, the device must be removed from the vagina or must be
30 collapsed to remove the pressure applied against the bladder neck. Trying to solve this problem, vaginal devices were developed in special shapes, without completely blocking the bladder neck so that the patient may urinate with the device in place (for example, US patents 6189535 B1, 6158435, 5894842, 5611768). These devices,

however, are generally large and intrusive and, therefore, are uncomfortable to wear, with low patient satisfaction and compliance. They are also relatively expensive, and therefore designed to be reusable.

5 There are several drawbacks of existing vaginal devices:

1. Most of them are intended to be reusable, hence they are made as resilient large bodies, made of plastic, hard rubber, or other such materials, in order to preserve their shape and function for a long time.
- 10 2. Insertion of large noncompliant bodies is sometimes difficult, painful or unpleasant, sometimes necessitating a medical practitioner. Removal causes same unpleasantness.
3. Most reusable devices are meant to remain in the vagina for prolonged periods of time, thereby causing irritations, pressure ulcers, infections, foul smelling discharge, etc.
- 15 4. Such reusable devices have a long standing bad reputation among patients and medical practitioners for being unpleasant, causing infectious discharge and foul odor, and being associated with disability and old age.
- 20 5. Some reusable devices are meant to be inserted daily by the patient, and to be removed after several hours, by means of pulling a string or with a finger, to be cleaned for re-use, and to be kept in certain conditions prior to following insertion. Some patients are reluctant to touch their selves in such intimate parts of their bodies, or disgusted to clean the device, hence their reluctance to use it.

Vaginal devices may cause two main side effects:

- 25 1. **Infections**-any foreign material, anywhere in the body, may become infected by several kinds of organisms, and cause formation of a foul smelly discharge. Reusable devices are certainly prone to cause such infections, but also, less frequently, disposable ones. In order to prevent such infections, devices should be:
 - 30 • disposable
 - used for a limited length of time, in order to prevent organism from growing, and to prevent damage, by vascular pressure, to the vaginal wall.

- made in a way that will allow vaginal or cervical normal secretions to flow out of the body
- made of certain known materials that would not permit growth of organisms.

5 2. **Pressure Necrosis** – prolonged pressure on the vaginal sidewalls may cause pressure on blood vessels with resultant necrosis, bleeding and infections. This might be prevented by using disposable devices only, for a predetermined length of time.

10

15

The invention

The invention will now be described with reference to accompanying drawings:

FIG. 2 is a side view of the female pelvis.

FIG. 3A is a top view of the invention partially covering a vaginal device.

5 FIG. 3B is a side view of the invention partially covering a vaginal device.

FIG. 4A is a sectional view of the invention. (Section A-A)

FIG. 4B is a sectional view of the invention. (Section B-B)

10 The device (FIG. 3) is intended to be applied into the vagina with an applicator much like the insertion of a regular menstrual tampon. After insertion, the device should expand significantly to the predefined shape and size, thereby exerting predefined appropriate pressure on both lateral vaginal walls, pushing them aside. The apex of the vagina shall be pushed upwards at the same time. That expansion of the device shall eventually create linear stretching of the anterior & posterior vaginal walls, while
15 creating a new shape of intra-vaginal hollow (rectangle). The device may be left inside the vagina for several hours. Removal for disposal will occur while pulling a string and collapsing the device to a much smaller size.

The vaginal device (FIG. 3A+B), looks like a round ring (50+52) and a string (54). It is made of elastic materials, such as silicon, polyurethane, etc. This flexible material gives
20 the device the ability to be folded into an applicator, and to be pushed out easily within small dimensions into the vagina.

On its outer surface, the device (50) is partially covered by an external soft layer (52) made of a much softer material, such as sponge rubber, etc., which makes it much more comfortable to wear. The sponge is also reducing the pressure on the vagina's sidewalls
25 and helps preventing pressure necrosis. This prevention of pressure takes place due to the spongy texture of the device, thus blood flow within the vaginal walls is not halted, and pressure necrosis is less likely to happen.

The presence of such a spongy layer further reinforce the friction between the device and the walls of the vagina, to further prevent unwanted movements or expulsion of the
30 device.

The spongy layer is situated on the external aspect of the device (FIG 3A+3B). In fact, only part of the external wall of the device (58) is covered (56) as is shown in FIG 4.

Alternative embodiments of the invention.

- 5
- The external soft layer may be made of several soft materials
 - Degree of coverage of the device with the spongy layer might be altered according to shape, pressure and size
 - Thickness of the spongy layer might also be changed.

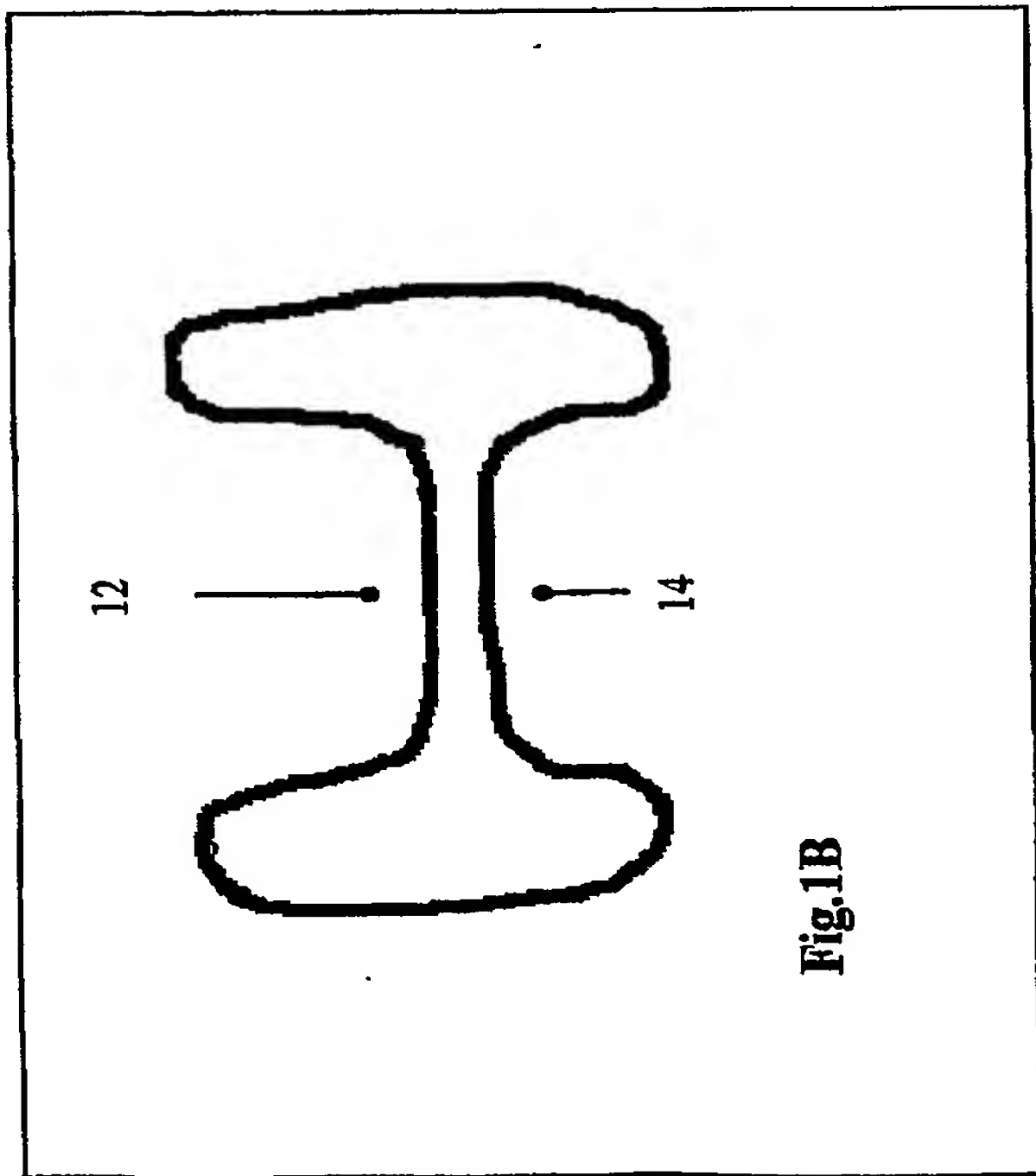


Fig.1B

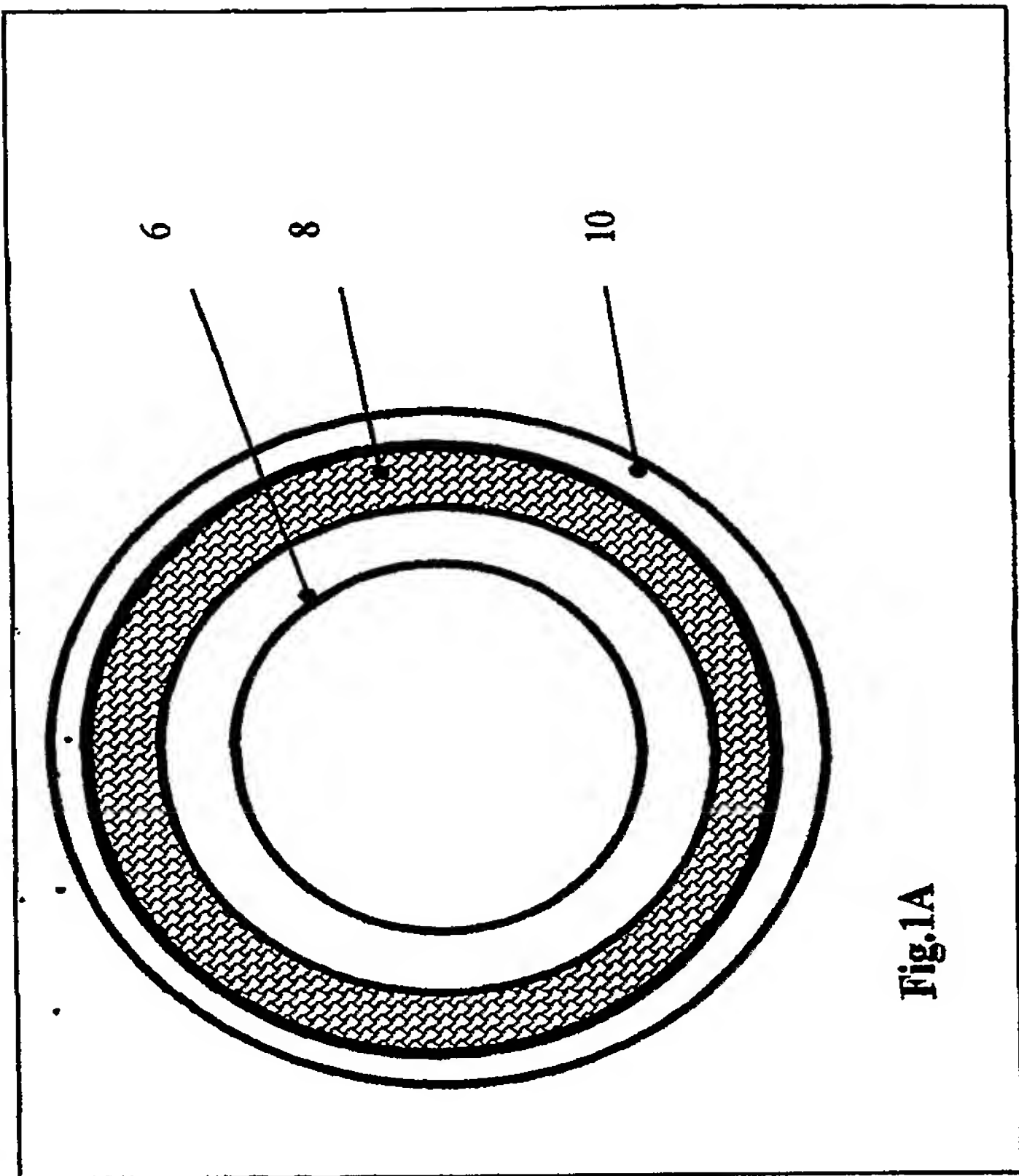


Fig.1A

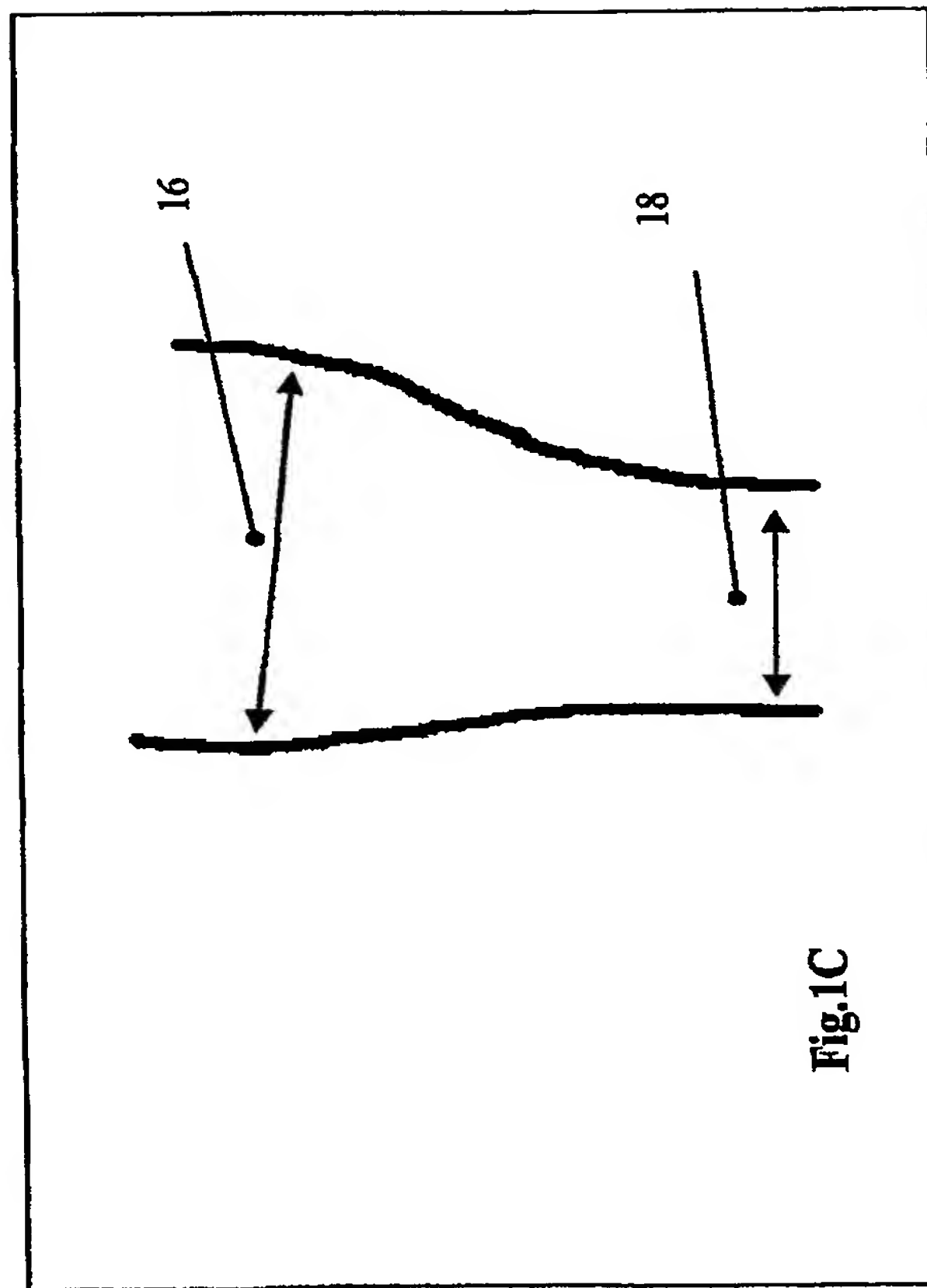


Fig.1C

A soft ring for prevention of vaginal wall necrosis in treatment of pelvic organ prolapse
Dr Elan Ziv, MD OBGYN, Urogynecologist

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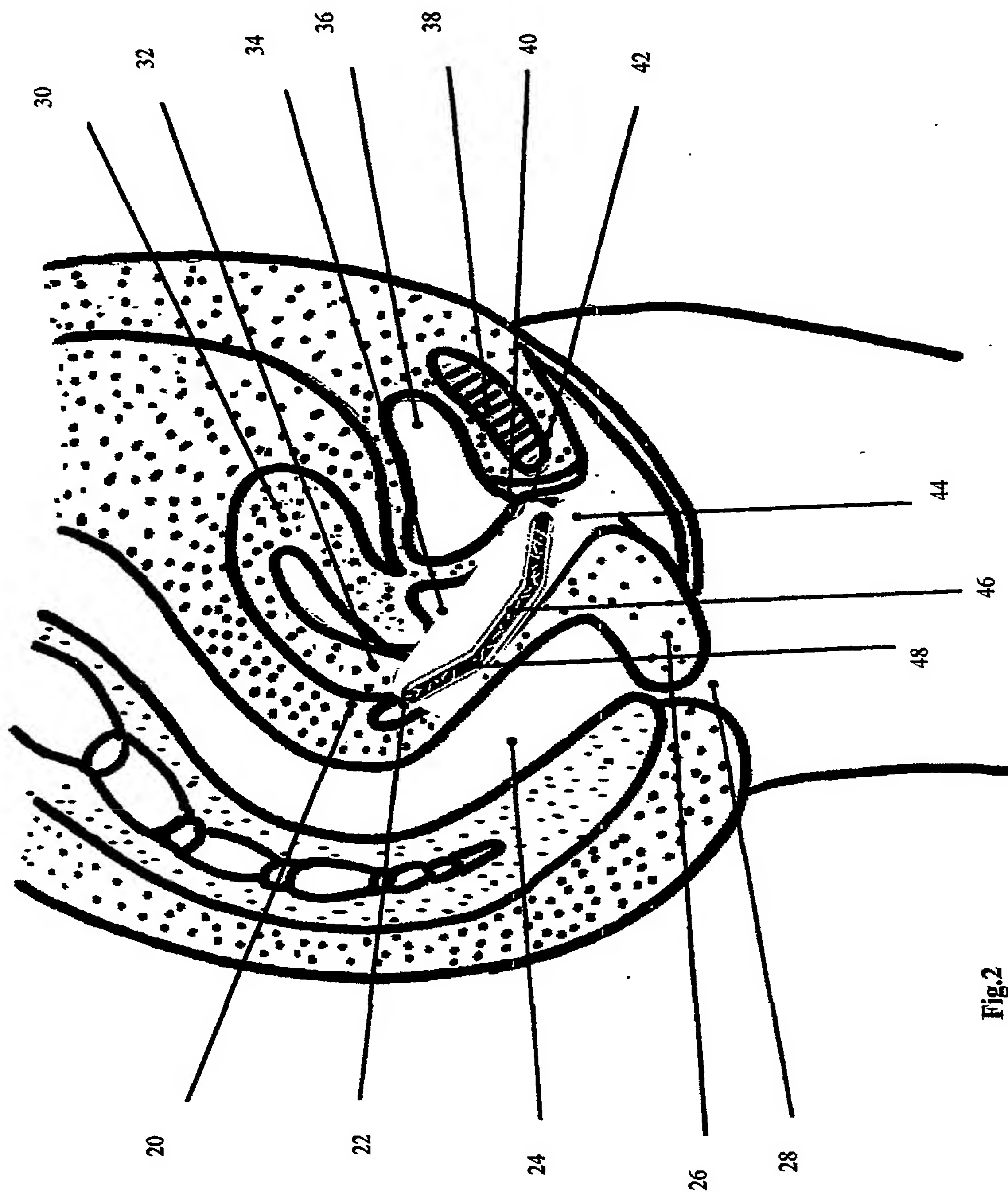
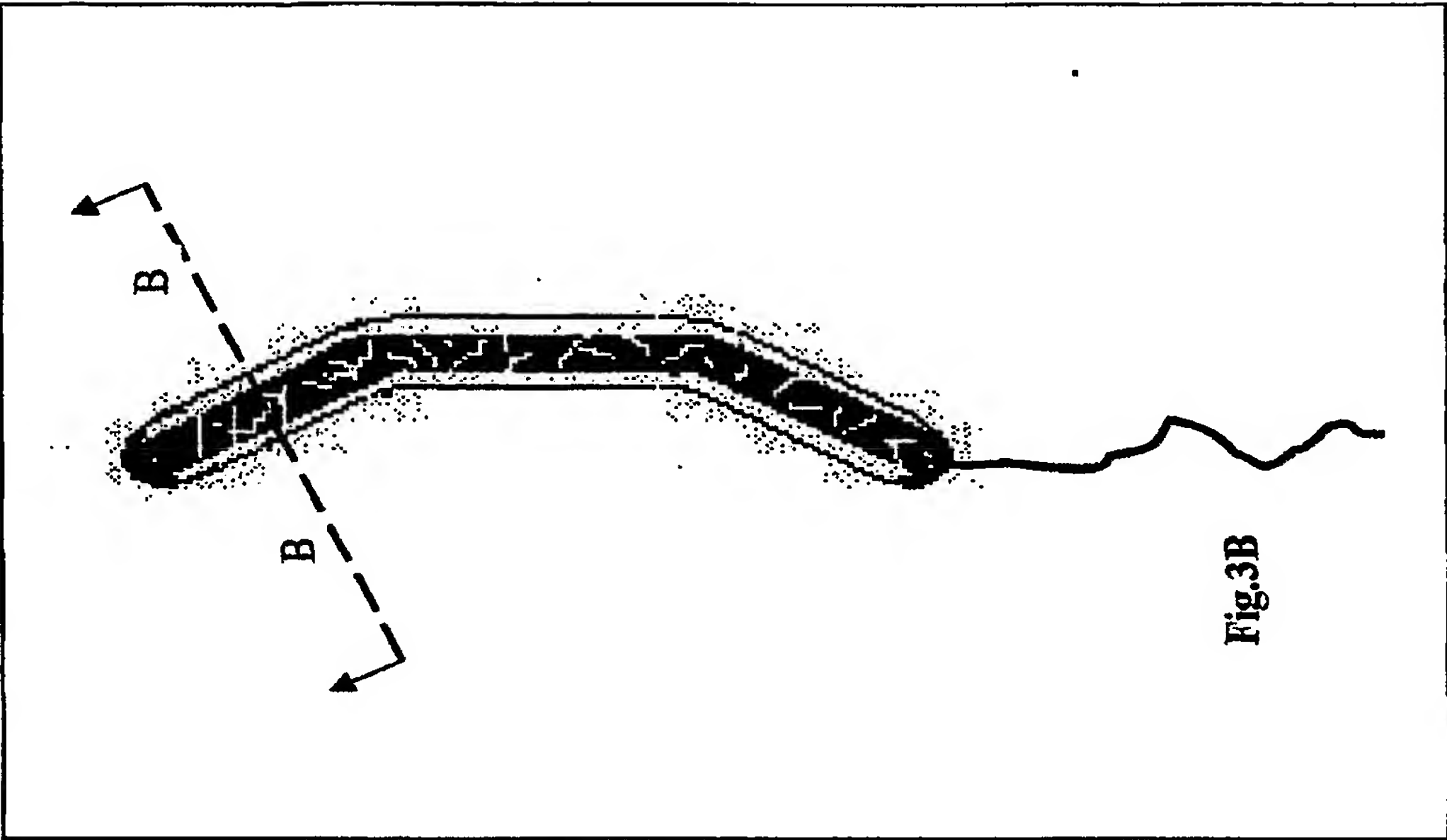
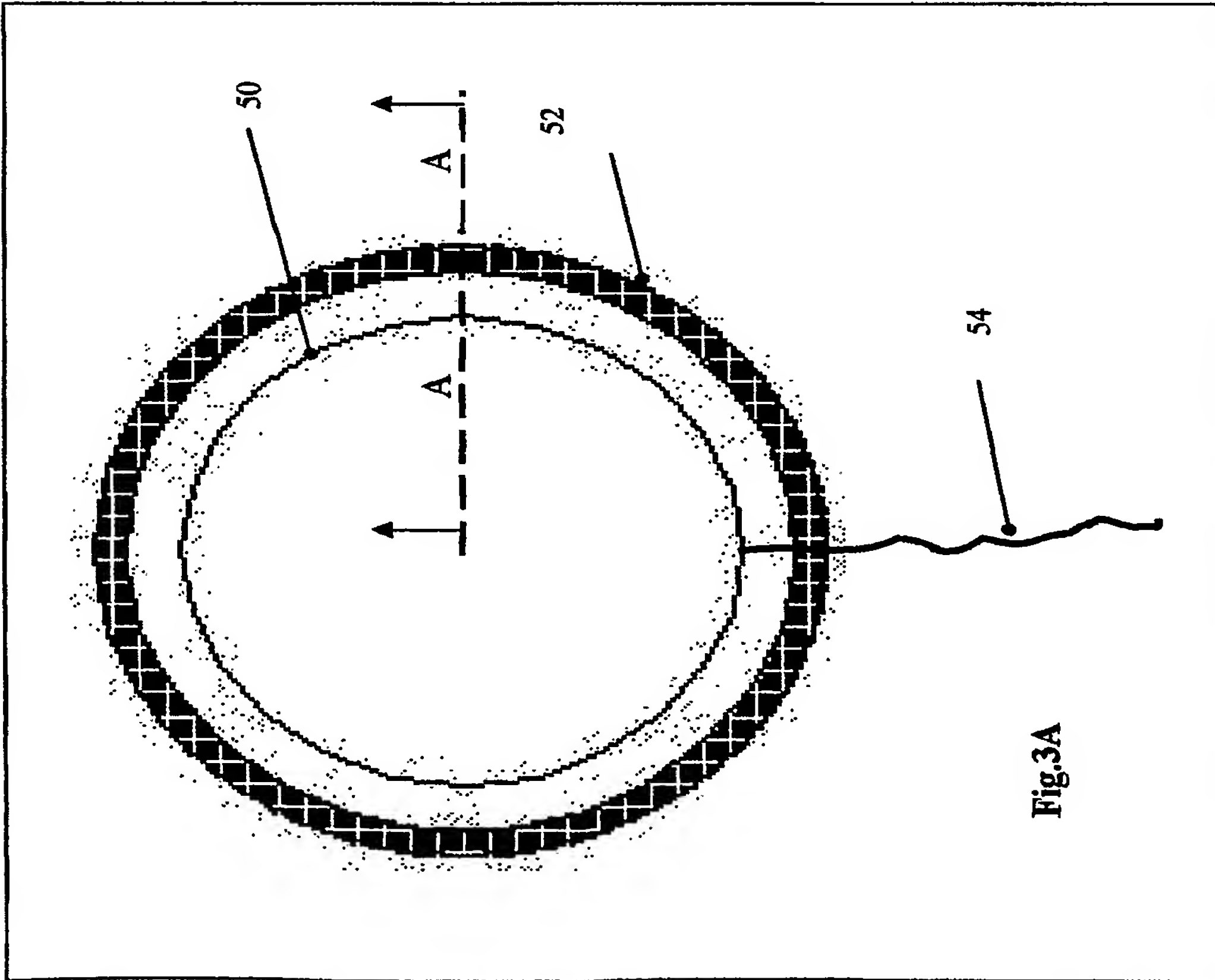


Fig. 2

A soft ring for prevention of vaginal wall necrosis in treatment of pelvic organ prolapse
 Dr Elan Ziv, MD OBGYN, Urogynecologist

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A soft ring for prevention of vaginal wall necrosis in treatment of pelvic organ prolapse
 Dr Elan Ziv, MD OBGYN, Urogynecologist

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View A-A

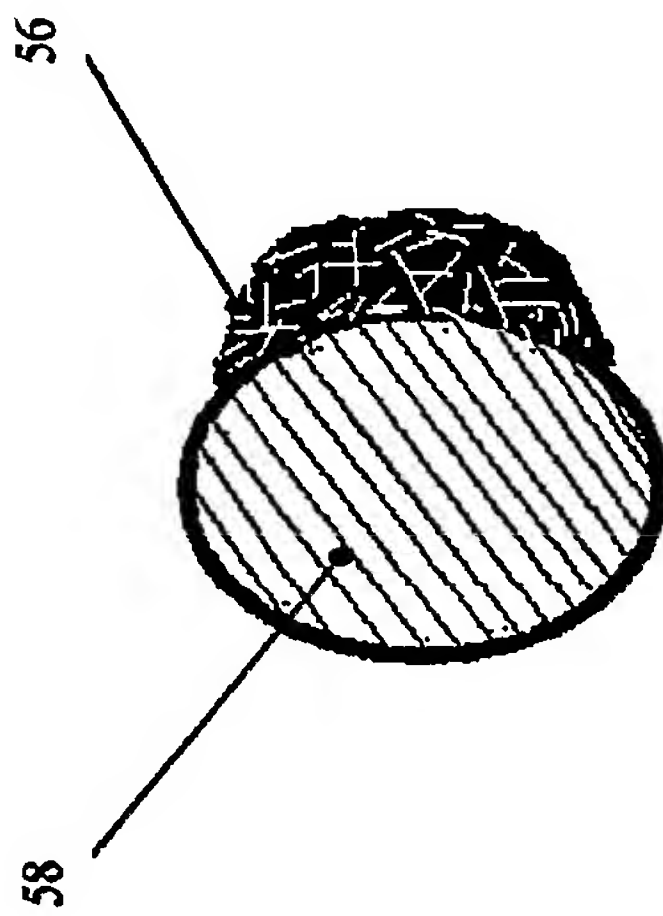


Fig. 4A

View B-B

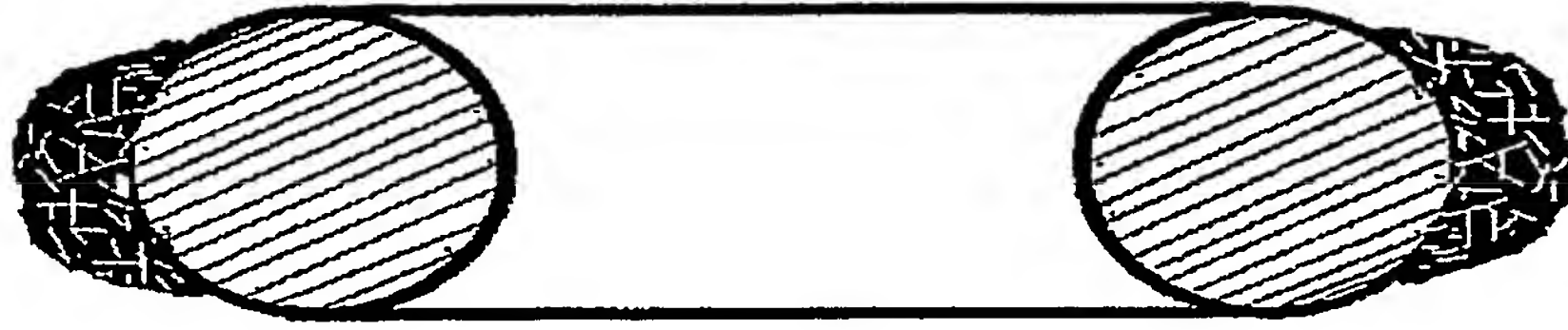


Fig. 4B

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A soft ring for prevention of vaginal wall necrosis in treatment of pelvic organ prolapse
Dr Elan Ziv, MD OBGYN, Urogynecologist